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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

ART UNIT	PAPER NUMBER
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7

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/626,127

Applicant(s)

GARGER ET AL

Examiner

Jezia Riley

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 2 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1 and 2 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____

18) ☐ Interview Summary (PTO-413) Paper No(s) ____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other

DETAILED ACTION

1. The art unit for this application has changed. Applicant is informed, that any future response should be directed to Art Unit 1656.

Specification

2. The disclosure is objected to because of the following informalities: In pages 58-69, applicants have cited aspects of the inventions in claim format which is inappropriate.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

4. Claims 1 and 2 are rejected under 35 U.S.C. 102(e) as being anticipated by Desnick et al. (5,401,650).

Desnick et al. reference relates to the production of biologically active human .alpha.-Gal A involving cloning and expressing the nucleotide coding sequences for the enzyme in eukaryotic expression systems. Successful expression and production of this

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significant for a number of reasons. Although the invention is described for α -Gal A, the methods and modifications explained may be analogously applied to the expression of other secreted proteins, and in particular, other lysosomal enzymes, including but not limited to α -N-acetylgalactosaminidase, and acid sphingomyelinase. In order to express a biologically active α -Gal A, the coding sequence for the enzyme, a functional equivalent, or a modified sequence, as described in Section 5.1, supra, is inserted into an appropriate eukaryotic expression vector, i.e., a vector which contains the necessary elements for transcription and translation of the inserted coding sequence in appropriate eukaryotic host cells which possess the cellular machinery and elements for the proper processing, i.e., signal cleavage, glycosylation, phosphorylation, sialylation, and protein sorting. Mammalian host cell expression systems are preferred for the expression of biologically active enzymes that are properly folded and processed; when administered in humans such expression products should exhibit proper tissue targeting and no adverse immunological reaction. Methods which are well-known to those skilled in the art can be used to construct expression vectors containing the α -Gal A coding sequence and appropriate transcriptional/translational control signals. These methods include in vitro recombination/genetic recombination. Alternative eukaryotic expression systems which may be used to express the α -Gal A enzymes are yeast transformed with recombinant yeast expression vectors containing the α -Gal A coding sequence; insect cell systems infected with recombinant virus expression vectors (e.g.,

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infected with recombinant virus expression vectors (e.g., cauliflower mosaic virus, CaMV; tobacco mosaic virus, TMV) or transformed with recombinant plasmid expression vectors (e.g., Ti plasmid) containing the .alpha.-Gal A coding sequence.

5. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821 (a)1 and (a)2. However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below:

On page 26 and 50, for example, amino acid sequences are cited without citing their corresponding SEQ ID NOs thus failing to comply with sequence rules as summarized above.

This is a non-compliance with the sequence rules due to a lack of a submitted computer readable sequence listing.

6. No claim is allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jezia Riley whose telephone number is 703-305-6855. The examiner can normally be reached on 9:00AM - 4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on 703-308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 and 703-305-6855.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

June 18, 2001


JEZIA RILEY